A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Terumo Cardiovascular Systems Corporation
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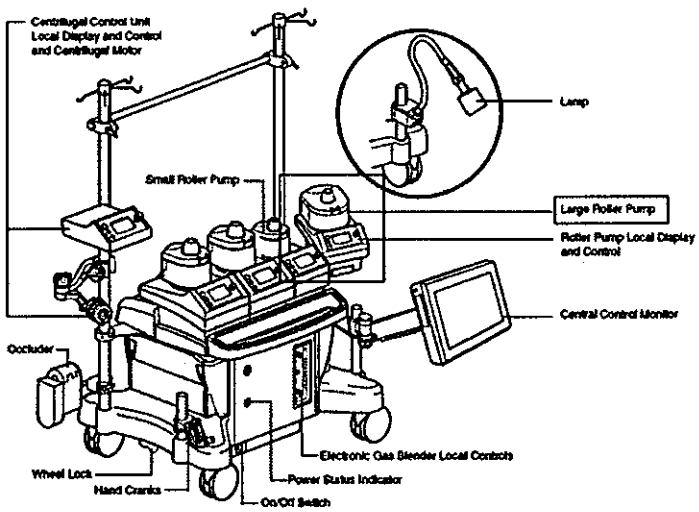
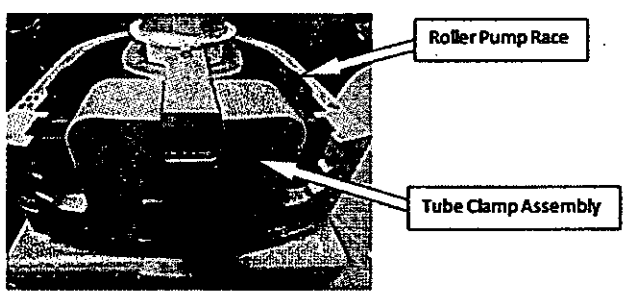
E-mail	Rebecca.andersen@terumomedical.com
Establishment Registration Number	1828100
Name of contact person	Rebecca Andersen
Submission Co-Authors	December 2, 2011
Date prepared	Terumo Cardiovascular Systems Corporation
Name of Device	
Trade or proprietary name	Large (6") Roller Pump for the Terumo® Advanced Perfusion System 1
Common or usual name	Cardiopulmonary Bypass Roller Pump
Classification name	Pump, blood, cardiopulmonary bypass, roller type
Classification panel	74 Cardiovascular
Regulation	21 CFR § 870.4370
Product Code(s)	DWB
Legally marketed device(s) to which equivalence is claimed	Sarns™ 8000 Roller Pump (K953901) Sarns™ 9000 Universal Roller Pump (K953904)
Reason for 510(k) submission	6" Large Roller pump for the APS1 – Redesign in support of Corrective Action: FDA Z-2735 to 2737-2011

Device description



Device Description: The APS 1 Large (6") Roller Pump is a peristaltic pump with a 6 inch diameter race. It can be mounted on the base of the Advanced Perfusion System 1 (APS1) console or can be positioned in an optimal location in the perfusion circuit by mounting on the pole. Pump operation can be configured using the APS1 Central Control Monitor (CCM). A local user interface display and control panel is also located on the front of the pump. The large roller pump can accommodate applications requiring flow rates up to 10 L/min including adult and pediatric arterial, cardioplegia, vent and suction pumping. The pump has a variable tube clamp mechanism that accommodates a variety of tubing sizes, including dual tube sets.

Indications for use



Indication for Use: The Large (6") Roller Pump for the Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

Summary of the technological characteristics of the device compared to the predicate device			
Characteristic	**Proposed Device: Large (6") Roller Pump for the APS 1 - (K112587)**	**Predicate# 1: Sarns™ 8000 Roller Pump (K953901)**	**Predicate# 2: Sarns™ 9000 Universal Roller Pump (k953904)**
Indication for Use	The Large (6") Roller Pump for the Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.	For use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures only, when used by a qualified medical perfusionist who is experienced in the use of Sarns™ or similar equipment	For use in extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures only, when used by a qualified medical perfusionist who is experienced in the use of Sarns™ or similar equipment
For Use With	Terumo Advanced Perfusion System 1	Stand alone or with Sarns™ 8000 Modular Perfusion System	Sarns™ 9000 Perfusion System
Functional Summary	Large roller pump is a peristaltic roller pump with 6" race and can accommodate applications requiring flow rates up to 10 L/min including • adult and pediatric	Peristaltic roller pump with 6" race can accommodate applications requiring flow rates up to 10 L/min including • adult and pediatric • arterial	Peristaltic roller pump with 6" race can accommodate applications requiring flow rates up to 10 L/min including • adult and pediatric • arterial

	• arterial • cardioplegia • vent • suction pumping	• cardioplegia • vent • suction pumping	• cardioplegia • vent • suction pumping
Tube Clamp Assembly	Variable tube clamp to accommodate a variety of tubing sizes, including dual tube sets. Does not require different size tubing inserts.	Tube clamp mechanism to accommodate a variety of tubing sizes including dual tube sets, through the use of various fixed inserts	Tube clamp mechanism to accommodate a variety of tubing sizes including dual tube sets, through the use of various fixed inserts
Tubing Requirements	• Medical Grade PVC tubing • 11/16" OD (max) • 1/16" – 3/32" wall thickness	• Medical Grade PVC tubing • ¾" OD (max) equals 12/16" • 1/16" – 3/32" wall thickness	• Medical Grade PVC tubing • ¾" OD (max) • 1/16" – 3/32" wall thickness
Panel Displays and Controls	Front panel for user interface controls, functional displays, and alarm conditions.	Front panel for user interface controls, functional displays, and alarm conditions.	Front panel for user interface controls, functional displays, and alarm conditions.
Pump Configurations / Modes	Pump can be configured using the APS1 Central Control Monitor (CCM) as: • Arterial pump • Cardioplegia pump Arterial pump can be run in Continuous, Pulse, Servo, or Master/Follower mode.	Pump can be configured via corresponding cable from Sarns base as • Arterial pump • Cardioplegia pump Arterial pump can be run in Continuous or Pulse mode. Pulse mode is enabled by connecting an optional Pulse Module.	Pump can be configured via corresponding cable from Sarns base as • Arterial pump • Cardioplegia pump Arterial pump can be run in Continuous or Pulse mode. Pulse mode is enabled by connecting an optional pulse module.
Internal Monitoring, Controls and Safety Features	Pump continuously monitors its own performance and reports	Pump continuously monitors its own performance and reports status	Pump continuously monitors its own performance and reports status

	status information and problems to the user via the pump display panel alarms and to the CCM, including: • Pump jam • Belt-slip • Over speed • Under speed • Internal temperature	information and problems to the user via the pump display panel alarms, including: • Pump jam • Belt-slip • Over speed • Under speed	information and problems to the user via the pump display panel alarms, including: • Pump jam • Belt-slip • Over speed • Under speed
Mounting	Pump can be mounted on APS 1 base or pole.	Pump is mounted on Sarns base.	Pump is mounted on Sarns base.
Dimensions (nominal)	Height: 12.5 in (31.8 cm) Width: 8.5 in (21.6 cm) Depth: 13.1 in (33.3 cm)	Height: 14 in (35.6 cm) Width: 8.2 in (20.8 cm) Depth: 19.7 in (50.0 cm)	Height: 8.0 in (20.3 cm) Width: 8.75 in (22.2. cm) Depth: 14.0 in (35.6 cm)
Weight (nominal)	26 lb (11.7 kg)	50 lb (22.6 kg)	31 lb (14 kg)
Power	Low voltage, 24v DC power and battery backup	Pump AC/DC power supply and battery backup	Low voltage, 24v DC power and battery backup
Flow Range	0 – 10 L/min	0 – 10 L/min	0 – 10 L/min
Speed Range / Accuracy	0 – 250 RPM ± 2 RPM or 1% of actual, whichever is greater	• 0 – 200 RPM ± 2 RPM • 200 – 258 RPM ± 1% of actual	0 – 245 or 255 RPM ± 2 RPM or 1% of actual, whichever is greater
Environmental Conditions (Operation)	• 10°C to 40°C • ≤ 75%RH • Non-condensing	• 10°C to 40°C • ≤ 95%RH • Non-condensing	• 10°C to 40°C • ≤ 75%RH • Non-condensing
Environmental Conditions (Storage)	• Store in ventilated area • -30°C to 54°C • ≤ 95%RH • Non-condensing	• Store in ventilated area • -30°C to 54°C • ≤ 95%RH • Non-condensing	• Store in ventilated area • -30°C to 54°C • ≤ 95%RH • Non-condensing

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

The APS1 Large Roller Pump was previously found substantially equivalent to the named predicate devices under K022947. The purpose of this 510(k), K 112587, is to document a design change to the tube clamp assembly. The change addresses a failure mode, discovered during postmarket surveillance, which results in failure.

Design and system verification and validation testing demonstrated that the modified design of the Tube Clamp assembly assures system reliability by enabling the internal assembly components to withstand impact forces that may be encountered during use.

Performance Test Summary-Proposed Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Strength	Design Verification Protocol: Knob/Cam Follower Impact Strength Verification	**Pass** – All pre-defined acceptance criteria met
Reliability/Durability	Design Validation Protocol: Simulated use testing on new and aged parts; multiple cycles under worst case conditions	**Pass** – All pre-defined acceptance criteria met

Summary of Non clinical tests conducted for determination of substantial equivalence
TCVS concludes that the Large 6" Roller Pump that is the subject of this 510k is substantially equivalent to the Sarns 8000, and 9000 Roller pump assemblies as cleared under K953901 and K953904. The devices have the same intended use and substantially equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 19 2011

Terumo Cardiovascular Systems
c/o Rebecca Andersen, Ph.D.
6200 Jackson Road
Ann Arbor, MI 48103

Re: K112587
Trade/Device Name: Large (6") Roller Pump for Terumo Advanced Perfusion System 1 (APS1)
Regulation Number: 21 CFR 870.4370
Regulation Name: Roller-type cardiopulmonary bypass blood pump.
Regulatory Class: Class II
Product Code: DWB
Dated: December 2, 2011
Received: December 6, 2011

Dear Dr. Andersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Terumo Cardiovascular Systems Corporation

Indications for Use

510(k) Number: K112587

Device Name: **Large (6") Roller Pump for the Terumo® Advanced Perfusion System 1**

The Large (6") Roller Pump for the Terumo® Advanced Perfusion System 1 is indicated for use for up to 6 hours in the extracorporeal circulation of blood for arterial perfusion, regional perfusion, and cardiopulmonary bypass procedures, when used by a qualified medical professional who is experienced in the operation of this or similar equipment.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112587

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